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EXAMINER

OLSON, ERIC

ART UNIT	PAPER NUMBER
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1623

NOTIFICATION DATE	DELIVERY MODE
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07/02/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/537,437

Applicant(s)

HARA ET AL.

Examiner

Eric S. Olson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 13, 14, 21, 24 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-8, 24 and 25 is/are rejected.
- 7) ☒ Claim(s) 13, 14 and 21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

This office action is a response to applicant's communication submitted April 19, 2007 wherein claims 1 and 3-5 are amended, claims 9-12, 15-20, and 22-23 are cancelled, and new claim 25 is introduced. This application is a national stage application of PCT/JP03/15336, filed December 1, 2003, which claims benefit of foreign application JP2002-352968, filed December 4, 2002, and JP2002-358249, filed December 10, 2002.

Claims 1-8, 13, 14, 21, 24, and 25 are pending in this application.

Claims 1-8, 13, 14, 21, 24, and 25 as amended are examined on the merits herein.

Applicant's amendment, submitted April 19, 2007, with respect to the rejection of instant claims 1-24 under 35 USC 112, for lacking enablement for the full range of fluorination substrates claimed, has been fully considered and found to be persuasive to remove the rejection as the claims as amended recite a narrower range of monosaccharides. Therefore the rejection is withdrawn.

Applicant's amendment, submitted April 19, 2007, with respect to the rejection of instant claims 4, 5, 18, and 21-23 under 35 USC 102(b), for being anticipated by Chirakal et al., of record in the previous office action has been fully considered and found to be persuasive to remove the rejection as the claims as amended are drawn to

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methods involving fluorinating agents not taught by Chirakal et al. Therefore the rejection is withdrawn.

Applicant's amendment necessitates the following new grounds of rejection:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the identity of general formula I. Because Applicant's amendment necessitated this new ground of rejection, the rejection is made **FINAL**.

The following rejections of record in the previous office action are maintained:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dmowski et al. (Reference included with PTO-892) Dmowski et al. discloses a fluorinating agent difluorobenzyl dimethylamine (DBDA). (p. 219, last paragraph) DBDA

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falls within the limitations of formula I in instant claim 1. DBDA is disclosed to be useful for the dehydrofluorination of primary alcohols, for example. (p. 221, first paragraph) Dmowski et al. does not disclose a method of fluorinating a monosaccharide using DBDA.

It would have been obvious to one of ordinary skill in the art at the time of the invention to fluorinate the primary alcohol of an appropriately protected saccharide using DBDA. (e.g. the 6- position of glucose) One of ordinary skill in the art would have been motivated to practice the invention in this manner because this position is a primary alcohol and DBDA is already disclosed to be useful for the dehydrofluorination of primary alcohols. One of ordinary skill in the art would reasonably have expected success because fluorinating the primary alcohol position of a saccharide is already included within the broad teaching of Dmowski et al. with respect to primary alcohols and because adapting a disclosed prior art reaction to a specific substrate having the same functionality is well within the ordinary and routine level of skill in the art, as is the selection of appropriate protecting groups for a particular reaction.

Response to Argument: Applicant's argument, submitted April 19, 2007, with respect to the above ground of rejection, has been fully considered and not found persuasive to remove the rejection. Applicant argues that the claimed fluorinating agents allow for selective fluorination at a specific position of a substrate, particularly a monosaccharide, and is compatible with protecting groups that would migrate or be eliminated under prior art fluorination conditions, thus producing unexpected selectivity over the prior art. However, according to MPME 716.02(d), Whether the unexpected

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results are the result of unexpectedly improved results or a property not taught by the prior art, the "objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support." In other words, the showing of unexpected results must be reviewed to see if the results occur over the entire claimed range. In re Clemens, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980) See also In re Peterson, 315 F.3d 1325, 1329-31, 65 USPQ2d 1379, 1382-85 (Fed. Cir. 2003); In re Grasselli, 713 F.2d 731, 741, 218USPQ 769, 777 (Fed. Cir. 1983) In the instant case, the scope of substrates covered by claims 1-3 is so broad as to include a wide variety of protecting groups and fluorination reactions well beyond the methyl glycosides for which unexpected results are alleged. For example, the claimed invention includes fluorination at the 1-, 2-, 3-, or 5- position of a saccharide, mono-, di-, tri-, and per- fluorination, and use of a wide variety of protecting groups and activating agents known in the art. Therefore Applicant fails to demonstrate unexpected results commensurate in scope with the claims.

For these reasons the rejection is deemed proper and made **FINAL**.

In a fax received May 29, 2007, Applicant suggested a proposed amendment to claim 1 that would, if entered, be persuasive to remove this rejection by amending the scope of reactants used to no longer include the species taught by Dmowski et al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

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obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 5-6 of U.S. Patent No. 7019173. (cited in PTO-892, herein referred to as '173) Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims 1-3 are an obvious specie of the claimed genus of claims 1-3 and 5-6 of '173.

Claims 1-3 and 5 of '173 are drawn to a method of fluorinating a substrate using a compound which is the same as the compound of formula I recited in instant claim 1. Claim 6 of '173 further limits the active group to a primary alcohol. Claims 1-3 and 5-6 of '173 do not explicitly claim a method of fluorinating a saccharide.

It would have been obvious to one of ordinary skill in the art at the time of the invention to practice the method of claims 1-3 and 5-6 of '173 on a saccharide as a substrate. One of ordinary skill in the art would have been motivated to practice the invention in this manner because a saccharide is a primary alcohol as recited by claim 6

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of '173. One of ordinary skill in the art would have reasonably expected success because adapting a reaction to a specific embodiment of a general teaching is well within the ordinary and routine level of skill in the art.

Response to Argument: Applicant's argument, submitted April 19, 2007, with respect to the above ground of rejection, has been fully considered and not found persuasive to remove the rejection. Applicant argues that claims 1-3, 5, and 6 of '173 do not teach a method wherein the material fluorinated is a monosaccharide or a monosaccharide bonded to the base of a nucleic acid. However, as discussed above, one of ordinary skill in the art would have recognized that this method could be used to fluorinate the primary alcohol group of an appropriately protected monosaccharide or a monosaccharide bonded to the base of a nucleic acid. Therefore the rejection is maintained and made **FINAL**.

Claims 4-8 and 24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 5 of copending Application No. 10/591698. (Cited in PTO-892, herein referred to as '698) Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are anticipated by claims 1-3 and 5 of '598.

Claims 1 and 2 of '698 is drawn to a method of fluorination comprising reacting a compound of general formula (I), which is the same between the instant application and '698, with a substrate. The substrate is a hydroxyl compound, and in one embodiment where $n=0$, is a diol. Claims 3 and 5 of '698 are drawn to methods in which the reaction

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is accelerated by microwave irradiation, as is the case in the claimed invention. Thus claims 1-3 and 5 of '698 anticipate the claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Argument: Applicant's argument, submitted April 19, 2007, with respect to the above ground of rejection, has been fully considered and not found persuasive to remove the rejection. Applicant argues that claims 1-3, 5, and 6 of '173 do not teach a method wherein the material fluorinated is a monosaccharide or a monosaccharide bonded to the base of a nucleic acid. However, as discussed above, one of ordinary skill in the art would have recognized that this method could be used to fluorinate the optically active diol group of an appropriately protected monosaccharide or a monosaccharide bonded to the base of a nucleic acid. Therefore the rejection is maintained and made **FINAL**.

Conclusion

Claims 1-8, 24, and 25 are rejected. Claims 13, 15, and 21 are objected to for depending from a rejected base claim but would be allowable if rewritten in independent form including all the limitations of the rejected base claims. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric Olson



Patent Examiner

AU 1623

1/4/07

Anna Jiang



Supervisory Patent Examiner

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